UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,539	08/22/2003	Jay Douglas Audett	ALZ5033USANP	9721

27777 7590 08/07/2007

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
CHANG, VICTOR S	

ART UNIT	PAPER NUMBER
1771	

MAIL DATE	DELIVERY MODE
08/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,539	AUDETT, JAY DOUGLAS	
	Examiner	Art Unit	
	Victor S. Chang	1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-16,18-23 and 25-36* is/are pending in the application.

4a) Of the above claim(s) *33-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-16,18-23 and 25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Introduction

1. Applicants' amendments and remarks filed on 6/26/2007 have been entered. Claim 31 has been amended. New claims 32-36 have been entered. Claims 14-16, 18-23 and 25-36 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. In response to the amendment, the grounds of rejection have been rewritten as set forth below.

Election/Restrictions

4. Newly submitted claims 33-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly added claims requires an additional backing layer, which carrying a primary or first drug, in addition to the backing layer carrying a secondary drug, therefore it changes the scope of the invention and is a species of distinct embodiment over the embodiment of original presentation. These distinct species are deemed to be patentable over each other.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, new claims 33-36 are withdrawn from consideration as being

directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 14-16, 18-23, 25-32 are active.

Double Patenting

5. Claims 14-16, 18-23, 25-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 13, 21, 43, 54-57, 66, 90-92, 97-99 of copending Application No. 10/420,428 in view of Steinborn et al. [US 6080421]. More particularly, the copending Appl. '428 discloses the structure and composition of the instant invention except that Appl. '428 is silent about that the outer layer is embossed. However, prior art Steinborn's invention relates to a multilayer transdermal identified without printing inks, and discloses that embossing or printing are known methods to label transdermal therapeutic systems. It would have been obvious to label the invention of copending Appl. '428 with the embossing method of Steinborn, motivated by the desire to be able to identify the device.

This is a provisional obviousness-type double patenting rejection.

Rejections Based on Prior Art

6. Claims 14, 15, 18-23, 25, 26, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kydonieus et al. [US 4758434] in view of Steinborn et al. [US 6080421], and evidenced by Gale et al. [US 4904475].

Kydonieus' invention [abstract; col. 9, lines 4-5 and 38-42] relates to an article for administering pharmacologically active substances (drugs) transdermally. Fig. 4 shows an

embodiment comprises a backing layer 34, a reservoir layer 35, and a diffusion membrane layer 36. The diffusion membrane layer 36 may be made of LLDPE (linear low density polyethylene). The backing is made of plastic, fabric, or aluminum foil.

For claims 14, 19 and 30, regarding the recited structural relationship between the layers (in terms the proximity to skin) merely defines the sequence of the layers as outer layer/tie layer/base layer. Regarding the use language in the preamble, since it fails to contribute or limit the structure and/or composition of the device, it has not been given patentable weight. Regarding the term "secondary drug reservoir", since the specification [0032] discloses that the secondary drug reservoir may contain either a beneficial agent (primary or first drug) or an antagonist, the term "secondary drug reservoir" is interpreted as merely meaning any "pharmacologically active drug". In other words, the term "secondary" is interpreted as a use limitation, therefore lacks any patentable significance. This interpretation is commensurate with the fact that, depending on the medical treatments, the same drug can be used either as a "primary drug" or an "antagonist" (secondary drug). For example, while naltrexone is used as an "antagonist" in the instant invention (see claim 26), it is known that the same drug has been used as a drug for transdermal use, i.e., primary drugs, as evidenced by prior art reference Gale et al. [col. 3, line 6]. Kydonieus' backing layer, reservoir layer and diffusion membrane layer structurally correspond to the outer layer, tie layer and base layer of the claimed invention. Kydonieus is silent about having an embossed outer layer. However, Steinborn's invention relates to a transdermal drug delivery system and discloses that embossing is a known procedure for labeling (identifying) a transdermal drug delivery system [col. 2, lines 7-8]. It would have been obvious to one skilled in the art of transdermal drug delivery system to emboss the outer

backing layer of Kydonieus' delivery system, as taught by Steinborn, motivated by the desire to provide identification.

For claim 15, absence of any composition limitation for the component layers in the tie layer, they are indistinguishable and fail to preclude a single tie layer of Kydonieus from reading on all the claimed component layers.

For claims 18, 23, 25 and 28, Kydonieus teaches that the outer backing layer 34 may also be a semi-permeable membrane, which clearly encompasses a microporous backing material [col. 9, line 51]. Further, the Official notice that "polypropylene microporous membrane is a common backing material for a transdermal delivery system" is now taken as admitted prior art.

For claims 20 and 26, Kydonieus discloses that the reservoir layer is a pharmacologically active agent containing plastisol (polymer matrix). Kydonieus' pharmacologically active agent clearly encompasses the claimed pharmaceutically acceptable salts.

For claims 21 and 22, Kydonieus discloses that pharmacologically active agents are dispersed in high concentrations in a plastisol formed by fusing PVC particles and plasticizers at elevated temperature (thermoformed) [col. 3, lines 54-55 and col. 2, lines 47-51]. Further, the Official notice that "dispersing particulate pharmacologically active agents in a polymer matrix for transdermal delivery system in not dissolved state is common and well known" is now taken as admitted prior art.

7. Claims 16, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kydonieus et al. [US 4758434] in view of Steinborn et al. [US 6080421] and FR 2249148 [Derwent abstract].

The teachings of Kydonieus and Steinborn are again relied upon as set forth above.

For claims 16, 31 and 32, Kydonieus lacks a teaching of a multilayer tie layer between the backing layer 34 (outer layer) and the reservoir layer 35. However, prior art FR '148 discloses that it is known that an adhesive tape of PET film having non-tacky hot melt EVA coating on both sides is used to join two surfaces and forms a bond by heat treatment. It would have been obvious to one of ordinary skill in the art to modify Kydonieus with an multilayered adhesive tape of FR '148 between the backing layer and the reservoir layer as well, motivated by the desire to provide an improved adhesion between the laminated layers.

8. Claims 27 and 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kydonieus et al. [US 4758434] in view of Steinborn et al. [US 6080421].

The teachings of Kydonieus and Steinborn are again relied upon as set forth above.

For claims 27 and 29, Kydonieus' backing layer 34, reservoir layer 35 and diffusion membrane layer 36 alternatively read on the base layer, tie layer and outer layer of instant invention, respectively. Since Kydonieus discloses that the backing layer 34 can be made of aluminum foil, it is inherently impermeable to drugs [col. 9, lines 4-5]. Again, regarding the use language in the claim, since it fails to contribute or limit the structure and/or composition of the device, it has not been given patentable weight. In particular, since the term "antagonist" merely a relative term opposite to "primary drug", and the same drug may be categorized differently in different conditions, therefore it fails to contribute structural limitation.

Response to Arguments

9. Pointing to a dictionary definition, applicant argues [Remarks 9] that since neither US Appl. No. 10/420428 nor Steinborn et al. have a multilaminate tie layer, which must include at

least two distinct layers together. However, since the dictionary definition states that "laminating" means "to make by uniting superposed layers of one or more materials", clearly the dictionary definition does not preclude one material in a single layer to read on all the layers in a multilaminate when the material (composition) is unspecified. The obviousness double patenting rejection is maintained. Further, since Appl. '428 discloses the structure and composition of the instant invention except that Appl. '428 is silent about that the outer layer is embossed, applicant's argument that neither reference talks about a backing that contains a drug is not taken.

Applicant argues [Remarks 10] that Kydonieus devices are transdermal drug delivery systems, not backings. Applicant further argues that the combination of Kydonieus and Steinborn will result in a drug delivery system to be used directly on skin, not a backing to be placed in a more complex drug delivery system. However, since statements of intended use do not serve to distinguish structure over the prior art, it has not been given any patentable weight. *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974).

Applicant argues [Remarks 11] that there is nothing to prevent the Kydonieus reservoir from delivering the "drug=antagonist" in the drug reservoir to the skin. However, since the terms "primary drug" and "antagonist" are exchangeable for the same drug under different treatments, they are interpreted as use language and have not been given patentable weight. Further, the combined teachings of Kydonieus and Steinborn read on the structure and composition as claimed.

Applicant argues [Remarks 12] that FR '148 is only an adhesive tape and totally unrelated to transdermal delivery. Applicant further argues that thick transdermal devices are

undersirable as they are cumbersome and unsightly. However, since the use language has not been given patentable weight and both the prior art references are directed to laminates structure, the examiner asserts that their combination is proper. Further, neither thickness nor appearance of the device is claimed features.

Regarding claims 27 and 29, applicant argues [Remarks 12] that if the backing layer of Kydonieus device is made of aluminum, it cannot be the base layer in a backing layer underneath a secondary drug reservoir. However, absent structure and composition limitations for the layers, Kydonieus' backing layer 34, reservoir layer 35 and diffusion membrane layer 36 read on the base layer, tie layer and outer layer of instant invention, respectively. Since the use language in the preamble has not been given patentable weight, Kydonieus' disclosure of an inherently impermeable aluminum foil backing layer reads on the instant invention as claimed.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H. Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victor S Chang/
Primary Examiner, Art Unit 1771

8/5/2007